

### REMARKS

Claims 1-8, 10-13, 15-26 and 28-49 are currently pending in this application.

Claims 1, 3, 8, 10, 12, 13, 15-17, 19-21, 26, 28, 30-33 are rejected. Claims 2, 4-7, 11, 18, 22-25, 29 and 34-49 are withdrawn.

#### Rejections under 35 U.S.C. 102

Claims 21, 26, 28, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarrow (U.S. Pat. No. 5,061,264). Applicants respectfully traverse as set forth below.

Scarrow discloses a fluid transfer system requiring an infusion bag (10) to be provided with a conduit (12) comprising a luer lock connector (16) and a rupturable fluid barrier (14) to enable it to be used with a socket portion (30) having a second luer lock connector (32). See FIG. 1.

In contrast, amended claim 21 is directed to a drug container configured for use with conventional infusion bags and containers. Specifically, the inlet port of a fluid container, e.g. infusion bag, does not have to be modified to include a luer lock (or other similar connector). Instead, as described at page 9, lines 8-11, in figure 5 and in original claim 16, connection is accomplished by inserting a hollow spike into the inlet port of the fluid container, with a first luer lock on the hollow spike for connection with a second luer lock associated with the drug vial/container.

Accordingly, Scarrow does not disclose at least "a drug container for use in an infusion system, comprising: . . . a cap for sealing said drug container, said **cap further comprising a luer-lock connector for attachment to a corresponding connector provided on a hollow spike that is arranged to be retained inside walls of an inlet port of a container for infusion fluid**, thereby creating a luer-lock coupling, said cap further comprising a protruding member forming a fluid duct between said drug container and said second luer-connector, wherein fluid

barrier able to be ruptured by an external force is provided inside said second fluid duct," as recited in amended independent claim 21. (emphasis added).

Accordingly, Applicants submit that claim 21 is patentable over Scarrow and request withdrawal of the rejection of claim 21 under Section 102. Applicants submit that claims 26, 28, 30, 32 and 33 are likewise patentable at least as depending from claim 21.

Rejections under 35 U.S.C. 103

Claims 1, 3, 8, 10, 12, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow in view of Shemesh et al. (U.S. Pat. No. 5,817,083).

Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow in view of Shemesh et al. and further in view of Haber et al. (U.S. Pat. No. 5,593,028).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow in view of Shemesh et al and further in view of Vaillancourt (U.S. Pat. No. 5,897,526).

Applicants respectfully traverse as set forth below.

Scarrow requires a luer lock connector on the modified infusion bag as discussed above. Similarly, Shemesh requires that the flexible tube (14) of the inlet port of an infusion bag be provided with means to connect the flexible tube (14) to the cap (16) of a drug container (4) and with a rupturable barrier (membrane 32) and means (34) to rupture the rupturable barrier (32). Vaillancourt similarly employs a special connector with the infusion bag. Haber is directed to a mixing and dispensing vial and does not address infusion bag inlet port connection.

In contrast, the claimed fluid transfer system provides a simple, reliable and safe way of transferring fluids to and/or from a fluid container, without the need for modification of the inlet port of the fluid container. Specifically, amended independent claim 1 recites a fluid transfer assembly comprising "a fluid container having an infusion fluid, . . . at least one fluid barrier controlling fluid passage between said drug container and said fluid container, said fluid

container further comprising at least one inlet port for receiving said medical substance from said drug container, a hollow spike member arranged to be retained inside walls of said inlet port and provided with a first luer-lock connector, said drug container further comprising a cap for sealing said drug container, said cap further comprising a second luer-lock connector for attachment to said first luer-lock connector, and wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage."

Thus, neither Scarrow, Shemesh, Haber, Vaillancourt or any combination thereof discloses or suggests at least the hollow spike connection with the fluid container and the luer lock connection with the drug container as recited in amended independent claim 1. Additionally, one of mere ordinary skill in the art in possession of the cited references would not arrive at the claimed configuration where the cited references teach modification of the infusion bag for connection to a luer connector or connection of the infusion bag tube to the cap of the drug container.

Accordingly, Applicants submit that claim 1 is patentable over the cited references and request withdrawal of the rejections under Section 103. Similarly, the respective dependent claims are likewise patentable as depending from claim 1.

### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

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No charges are believed due. However, if any fees are due, they are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050

Respectfully submitted,

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